U. S. Department of Energy

Consolidated Audit Program

Module 2

Checklist for Organics

Revision 2
February 17, 2004

Audit ID:

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
2.1	**Standard Operating Procedures**		
2.1.1	The laboratory has Standard Operating Procedures (SOPs) for the following: • Sample management; • reagent and standard preparation; • general laboratory techniques; • test methods; • equipment calibration and maintenance; • quality control; • corrective action; • data reduction and validation; • reporting; • records management; and, • waste manual. *(SW-846 Chapter One, Section 4.3 Quality Systems for Analytical Services, 10.1.1)*		
2.1.2	The laboratory shall have and maintain an in-house methods manual(s) for each accredited analyte or test method. The manual may consist of copies of published or referenced test methods or standard operating procedures that have been written by the laboratory. Each method shall contain: • identification of the test method; • applicable matrix or matrices; • detection limit;		

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2.1.2 (Cont'd)	• scope and application, including components to be analyzed; • summary of the test method; • definitions; • interferences; • safety; • equipment and supplies; • reagents and standards; • sample collection, preservation, shipment, and • storage; • quality control; • calibration and standardization; • procedure; • calculations; • method performance; • pollution prevention; • data assessments and acceptance criteria for quality control measures; • corrective actions for out-of-control data; • contingencies for handling out-of-control or unacceptable data; • waste management; • references; and, • any tables, diagrams, flowcharts, and validation data. *(SW-846 – Chapter One, Section 4.3 Quality Systems for Analytical Services, 10.1.2a and b)*		

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2.1.3	Laboratory notebooks (logbooks) comply with the following: • are controlled through a documented system; • have sequentially numbered pages; • entries are dated and signed by the person responsible for performing the activity at the time the activity is performed; • entries are in chronological order; and, • protected against damage, deterioration, or loss. (*Quality Systems for Analytical Services, 12.2d)*		
2.1.4	A system is in place to ensure that quality records are legible, accurate, and complete, e.g., independent review of records, logbooks, etc. *SW-846 – Chapter One, Section 4.6, Quality Systems for Analytical Services, 12.1)*		
2.1.5	Corrections to documents that will become quality records are made by drawing a single line through the error, initialing the error, and justifying the correction, if non self-explanatory. *(Quality Systems for Analytical Services, 12.1f)*		
2.2	**Sample Preparation/Extraction**		

Status Key: A = Acceptable, U = Unacceptable, NA = Not Applicable, F = Finding, O = Observation

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2.2.1	In order to minimize instrument contamination and downtime, the laboratory employs a sample screening procedure prior to extraction and analysis. *(SW-846 – Method 8000B, Section 3.2)*		
2.2.2	The laboratory has a documented procedure for the determination of extraction level. *(SW-846 – Chapter One, Section 4.3.4)*		
2.2.3	Glassware and containers are either designated as disposable or cleaned according to a Standard Operating Procedure. *(SW-846 – Chapter One, Section 4.3.3; Quality Systems for Analytical Services, 9.4.1e)*		
2.2.4	The laboratory-specific Standard Operating Procedure (SOP) for glassware is available to applicable laboratory personnel. *(SW-846 – Chapter One, Section 4.3 and 4.3.3, Quality Systems for Analytical Services, 7.2c)*		
2.2.5	General Facility: • laboratory is clean and organized; • sample preparation is performed on a clean		

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	tabletop; • hoods are clutter free; and, • adequate workspace. *(SW-846 – Chapter One, Section 4.1, Quality Systems for Analytical Services, 7.2c and d)*		
2.2.6	Balances are checked each day that they are used and are calibrated at least annually by an independent company or source. *(Quality Systems for Analytical Services, 9.4.1b and d)*		
2.2.7	Check weighing performed daily using NIST traceable weights. Daily checks documented in controlled logbooks. *(Quality Systems for Analytical Services, 9.4.1b and d)*		
2.2.8	Liquid in-glass thermometers are calibrated against a NIST traceable standard at least every five years. *(Quality Systems for Analytical Services, 9.4.1b)*		
2.2.9	The accuracy of all non-Class A pipettes and automatic sample dispensers used for quantitative measurement is verified monthly or whenever degradation of measuring equipment is suspected.		

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	(Quality Systems for Analytical Services, 9.4.1e)		
2.2.10	Refrigerator temperatures are monitored daily and recorded in a logbook or via electronic media such as a data logger. *(Quality Systems for Analytical Services, 9.4.1d)*		
2.2.11	A refrigerator storage blank is present for the storage of all volatile organic samples. Specific procedures for assessing the adequacy of these storage bank data and taking action for nonconforming conditions is established. The refrigerator blank is analyzed every 14 days when samples are being stored in the laboratory. The data from the analysis of the refrigerator storage blank is available for review. *(Quality Systems for Analytical Services, 11.4.a.3)*		

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2.2.12	Sample preparation documents indicate the following: • extraction procedure; • matrix; • identification number of standards and spikes added; • spike composition; • blanks; • volume/concentration of standards/spikes added; • name of analyst; • volume/weight of sample used; • final concentrated volume; • dilution information; • cleanup steps; • reagent log numbers; • start/stop dates/time for soxhlet and continuous liquid/liquid extraction; and, • observations. *(SW-846 – Chapter One, Sections 4.3.4 and 4.3.10 and 4.6)*		
2.2.13	Sample preparation practices assure homogenization so that a representative aliquot is obtained for analysis. *(SW-846 Method Specific Section 7.1)*		

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2.2.14	Dilutions of volatile organic samples for purge and trap analysis are not made using volumes less than one mL. *(SW-846 – Method 3550B, Section 7.0 and Quality Systems for Analytical Services, 9.4.1g)*		No reference available.
2.2.15	Sonication equipment is tuned prior to use to ensure optimum performance. *(SW-846 – Method 3550B, Section 7.0 and Quality Systems for Analytical Services, 9.4.1g)*		
2.2.16	For solids extraction using ultrasonic extraction, surrogate and spiking solutions are added to the solid prior to adding extraction solvent. *(SW-846 – Method 3550, Section 7.3)*		
2.2.17	Each analytical batch includes; • 20 samples or less; • method blank; • laboratory control sample; and, • matrix spike/matrix spike duplicate or laboratory control spike duplicate. *(Quality Systems for Analytical Services, Appendix D.1.1)*		

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2.2.18	Chain of Custody is transferred to the extraction laboratory and analytical laboratory through a documented sign off. *(Quality Systems for Analytical Services, 11.3.f)*		
2.3	**Clean Up Methods**		
2.3.1	The laboratory maintains and follows SOPs for all clean-up methods performed at their facility including, but not limited to: • gel-permeation Chromatography (GPC); • florisil; • silica gel; • alumina; and, • sulfur cleanup. *(SW-846 – Chapter One, Section 4.3)*		
2.3.2	The laboratory selection of cleanup methods is appropriate for the matrix of concern and for the potential interference. *(SW-846 – Method 8000B, Section 3.4; Method 3600C, Sections 1.0 and 7.3)*		

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2.3.3	When sample extracts are subjected to cleanup procedures, the associated method blank is subjected to the same cleanup procedure. *(SW-846 – Method 8000B, Section 8.2.6.4)*		
2.3.4	The GPC is calibrated at least once a week during operation. *(SW-846 – Method 3640A, Section 7.2)*		
2.3.5	When GPC is used, final sample concentration calculations account for the volume of sample lost in the dump of the instrument. *(SW-846 – Method 3640A, Section 7.7)*		
2.3.6	Instrument and maintenance logs are maintained for the GPC. *(Quality Systems for Analytical Services, 8.0e)*		
2.3.7	Florisil lot checks are performed to ensure adequate recovery of target analytes and adequate exclusion of interferences (e.g., trichlorophenol). *(SW-846 – Method 3620B, Section 8.0)*		

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2.3.8	Biological matrices are cleaned using a method that effectively excludes fats and lipids (e.g., sulfuric acid and cleanup).		
2.3.9	Sulfuric acid cleanup is not used for analytes that are destroyed by acids (e.g., some pesticides and herbicides) *(SW-846 – 3665A, Section 1.1)*		
2.4	**Instrument Calibration**		
2.4.1	Controlled procedures are present at the workstation that list requirements for instrument calibration and tuning. *(SW-846 – Chapter One, Section 4.3.5, Quality Systems for Analytical Services, 10.1.1c and e)*		
2.4.2	Out-of-calibration equipment is tagged or segregated and not used until it has been re-calibrated *(Quality Systems for Analytical Services, 8.0c and d)*		

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2.4.3	Equipment consistently found to be out of calibration is repaired or replaced. *(Quality Systems for Analytical Services, 8.0c*)		
2.4.4	If a linear calibration is to be used: • the relative standard deviation for calibration standard response meets defined acceptance criteria or linear calibration least squares regression meets defined acceptance criteria and, • curve is not forced through zero. *(SW-846 – Method 8000B, Section 7.5)*		
2.4.5	The laboratory follows a documented procedure for the determination and verification of retention time windows for GC and HPLC methods that do not employ internal standard calibration. *(SW-846 – Method 8000B, Section 7.6)*		

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2.4.6	For GC analysts, retention time windows are established for each analyte of concern and each column. (NOTE: in some cases pattern recognition can be used in lieu of retention time identification). *(SW-846 – Method 8000B, Section 7.6.6)*		
2.4.7	Retention time windows are established so as to minimize false positive or false negative results. *SW-846 – Method 8000B, Section 7.6 and Quality Systems for Analytical Services, Appendix D.1.5)*		
2.4.8	Procedures are in place to monitor the performance of the internal standard retention times and areas for all calibration standards, samples and blanks. *Quality Systems for Analytical Services, D.1.5)*		

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2.4.9	Initial calibration data are well documented for each instrument/detector including: • ID of standard used; • time of injection; • analyst; • detector/instrument ID; and, • calibration date. *(Quality Systems for Analytical Services, 9.4.2.1b)*		
2.4.10	Acceptance criteria are defined and documented for all initial calibration, continuing calibration and tuning requirements. *(Quality Systems for Analytical Services, 9.4.2.1e and 9.4.2.2d and Appendix D3.1.5c)*		
2.4.11	Continuing calibration checks, confirm sustained acceptability of initial calibration. *(Quality Systems for Analytical Services, 9.4.2.2)*		
2.4.12	Full calibration is performed if continuing calibration checks are unacceptable. *(Quality Systems for Analytical Services, 9.4.2.2e)*		

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2.5	**Standards and Reference Material**		
2.5.1	Regent grade or higher purity chemicals shall be used. Reagents shall be checked prior to use and the supporting documentation of the checks shall be filed in a manner that is easily retrievable. *(SW-846 – Method 8000B, Section 5.0; Quality Systems for Analytical Services, 10.5a)*		
2.5.2	If the initial calibration is not verified using an independent source, the LCS is prepared from an independent source. *(SW-846 Method 3500B, Section 5.3; Method 8260B, Section 5.13.2, Quality Systems for Analytical Services, 3.0)*		
2.5.3	Labels for purchased stock mixtures and reagents contain the following information: • date received; • date opened; and, • expiration date. *(Quality Systems for Analytical Services, 10.5a and b)*		

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2.5.4	Secondary standard solutions are traceable to a standards preparation log and labeled with the following information: • secondary standard tracking identification number; • preparer's initials; • preparation date; and, • secondary standard expiration date. *(Quality Systems for Analytical Services, 10.5c and d)*		
2.5.5	Calibration standards are assigned a unique identification number traceable to the original standards and an expiration date. These numbers and dates are placed on the standards container. *(Quality Systems for Analytical Services, 10.5.d)*		
2.5.6	Standards and reference materials are traceable to EPA or NIST certified standards, including: • initial calibration standards; • continuing calibration standards; • spiking standards; and, • surrogates. *(SW-846 Method Section 5.0, Quality Systems for Analytical Services, 9.2)*		

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2.5.7	Calibration standards are prepared using certified standards traceable to a nationally recognized or consensus source, and the certificates of authenticity are kept on file. *(Quality Systems for Analytical Services, 9.2)*		
2.5.8	Standards and reference materials are stored separately from samples and standards are protected in a controlled cabinet or refrigerator. *(Quality Systems for Analytical Services, 10.5.a)*		
2.5.9	Organic standards are properly refrigerated and stored as required by the specific EPA method. *(Quality Systems for Analytical Services, 10.5.a)*		
2.5.10	The laboratory has a procedure in place to track the expiration date of standards and removes standards from use when expired. *(Quality Systems for Analytical Services, 10.5.a)*		

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2.5.11	The following calibration criteria are met: • appropriate number, type and range of calibration standards are used as required by the EPA method; • for each analyte and surrogate of interest, initial calibration standards are prepared at a minimum of 5 different concentrations. *(SW-846 – Method 8000B, Section 7.4.4.1 and 7.4.1.4)*		
2.6	**Method Proficiency**		
2.6.1	The laboratory has performed and documented the results of a method validation study for each method. *(Quality Systems for Analytical Services, 10.2b and 10.2.1a)*		
2.6.2	Samples with concentrations that exceed the calibration range must be diluted to fall within the range. *(SW-846 – Method 8000B, Section 7.5 and Quality Systems for Analytical Services, 9.4.2.1.f)*		

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2.6.3	Samples initially diluted that have no identified compounds are re-analyzed at a lower dilution. Reported results are corrected for sample weight and moisture. *(Quality Systems for Analytical Services, 9.4.2.1f)*		
2.7	**Method Detection Limit (MDL) Determination**		
2.7.1	A procedure is in place for the determination and documentation of method detection limits for each organic method performed by the laboratory. The laboratory maintains procedures for determining for limits of detection and the frequency of verification. *(Quality Systems for Analytical Services, 5.4a)*		
2.7.2	Original documentation of method detection limit determinations including chromatograms and calculations is available for review. *(SW-846 – Chapter 1, Section 4.4.1, Quality Systems for Analytical Services Appendix D-1.2)*		

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2.7.3	MDLs are developed by method for the following: • each instrument configuration; • each matrix; and, • on both columns for methods requiring second column confirmation. *(Quality Systems for Analytical Services Appendix D-1.2)*		
2.8	**Instrument Run Logs**		
2.8.1	GC and GC/MS instrument run logs include: • data file names and address; • notation for any failure where the sample is to be re-run at a later time; • notation for reanalysis that references the original run when any failure occurred; • reference the original run for diluted samples when the calibration range was exceeded; • reference the sample purge manifold port used for VOCs; and, • decontamination activities documented. *(SW-846 – Chapter One, Section 4.6)*		

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2.9	**Carryover Minimization**		
2.9.1	An instrument (solvent) blank is analyzed when the previous sample showed the presence of an analyte at a high concentration. (*SW-846 - Method 8000B, Section 3.1*)		
2.9.2	A blank is run following the calibration verification standard to ensure the standard is purged from the system and will not carryover to subsequent samples. (*SW-846 – Method 8000B, Section 8.2.6.3*)		
2.10	**Spike Recovery Requirements**		
2.10.1	The methods for establishing acceptable ranges for spike recoveries and calibration check samples are defined and documented by the laboratory. (*SW-846 – Chapter 1, Section 4.4*)		
2.10.2	The analysts are following the steps specified in the SOP when spike recoveries and calibration check samples fall outside control limits. (*SW-846 – Chapter One, Section 4.4*)		

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2.10.3	The laboratory Quality Control manager or his/her designee periodically reviews control charts at a specified frequency for out of control conditions and initiates appropriate corrective action procedures. *(Quality Systems for Analytical Services 4.2g)*		
2.10.4	Statistical Control Charts are: • maintained for precision and accuracy; • updated in a real time manner; and, • accessible to the individual performing the analysis. *(Quality Systems for Analytical Services 5.4b)*		
2.11	**Second Column Confirmation**		
2.11.1	The laboratory has documented procedures and possesses equipment to perform second-column confirmation verification of results when required by the method or the laboratory SOP for a given method. (*SW-846 – Chapter One, Section 4.3*)		

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2.11.2	Columns are uniquely identified in such a manner that facilitates differentiation between results obtained from the primary column and those obtained from a secondary column.		
2.11.3	The confirmatory column contains a different stationary phase from the primary column. (*SW-846 - Method 8000B, Section 7.9*)		
2.11.4	Analyses performed on a secondary (confirmatory) column meet all required QC criteria. (*SW-846 - Method 8000B, Section 7.9*)		
2.12	**Batch Quality Control**		
2.12.1	The laboratory has made provision for the following as they relate to the different QC levels: • analysis of method and reagent blanks; • analysis of duplicates, spiked samples, spiked laboratory blanks, and reference or control standards such as EPA check standards; • criteria used to establish warning and control limits for the above types of QC samples; • documentation and examples of control data and control charts;		

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2.12.1 (Cont'd)	• the frequency of analyzing blanks and other QC samples; • how data from QC samples are reported and reviewed; and, • who reviews and makes decisions relative to QC data. *(SW-846 – Chapter One, Section 4.0)*		
2.13	**Analytical Worksheets**		
2.13.1	Analytical worksheets include, at a minimum: • name of the person performing the analysis; • instrument used in the analysis (If the subcontract laboratory has more than one instrument of a particular model, a unique designation shall be given to each); • name or initials of the peer, supervisory, or QA reviewer; • calibration information for all analytical work information on standards used during the analysis; • analytical procedure used; • equations for calculations used to obtain results (If instrument readouts give results, without the need for further mathematical manipulation, the worksheets shall include the statement "result = instrument readout"; and • date and time that the analysis was performed. *(SW-846 – Chapter 1, Section 46)*		

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2.14	**Instrument Operations**		
2.14.1	A system is in place to address instrument operational problems. This system should include the following elements: • fault finding/troubleshooting; • determining instrument problems via chromatographic examination; • procedures to repair malfunctioning equipment; and, • actions to be taken to prevent recurrence. *(SW-846 Method 8000B, Section 8.2, Quality Systems for Analytical Services 10.1.1e)*		
2.14.2	Analysts are familiar with chromatographic anomalies and the instrument conditions that cause them. *(SW-846 Method 8000B, Section 8.2)*		
2.14.3	The laboratory maintains a current list of equipment types, models and year of manufacture. *(Quality Systems for Analytical Services 8.0e)*		

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2.14.4	The laboratory maintains an in-house inventory of replacement parts for equipment and instruments or has a service contract for instrumentation. (*SW-846 – Method 8000B, Section 4.11 and Quality Systems for Analytical Services 8.0e)*		
2.14.5	The laboratory has established a schedule for routine instrument maintenance. *(Quality Systems for Analytical Services 8.0b and 8.0e)*		
2.14.6	Maintenance performed on analytical instrumentation is recorded in a logbook. *(Quality Systems for Analytical Services 8.0e)*		
2.14.7	Instrument modifications are documented in a permanent record. *(Quality Systems for Analytical Services 8.0e)*		
2.14.8	Instruments are connected to a source of stable power or surge protection devices are used. *(SW-846 – Chapter 1, Section 4.1)*		

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2.15	**Contamination Control**		
2.15.1	Engineering and/or administrative controls are in place to effectively eliminate contamination of samples or extracts by airborne or other means: • samples and solvents stored to prevent contamination; • adequate ventilation of work areas; • separation between extraction and instrument areas; • unused or excess samples are not stored in extraction or instrument areas; and, • GC/EC instruments are vented to the outside of the facility or to a trapping system. *(Quality Systems for Analytical Services 7.2)*		
2.15.2	The laboratory has a system in place to record incidents involving spillage of reagents and client samples. *(Quality Systems for Analytical Services 6.2d)*		

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2.15.3	If contamination is discovered, the laboratory has a corrective action plan in place to: • identify and eliminate the source; • determine which samples may have been impacted; and, • implement measures to prevent recurrence *(Quality Systems for Analytical Services 7.2d)*		
2.16	**Data Review**		
2.16.1	A data review procedure is in place that includes both analyst and independent data reviewer. *(SW-846 – Chapter 1, Sections 2.6 and 4.4.6, Quality Systems for Analytical Services 10.4b)*		
2.16.2	Data review is inclusive of all quality related steps in the analytical process including sample preparation, dilution calculations, chromatography and spectral interpretations. *(SW-846 – Chapter 1, Sections 2.6 and 4.4.6)*		

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2.16.3	Data review is documented and records are maintained. *(SW-846 – Chapter 1, Sections 2.6 and 4.4.6)*		
2.16.4	If manual transcriptions or data entry occur, these steps are identified and special controls are in place to check for human errors. *(SW-846 – Chapter 1, Section 4.4.6, Quality Systems for Analytical Services 12.3.3e)*		
2.16.5	The laboratory has established an SOP addressing manual calculations including manual integration. *(Quality Systems for Analytical Services 10.4)*		
2.16.6	Spreadsheets used for calculations shall be verified before use and documentation shall be readily available for review. *(SW-846 – Chapter One, Section 4.4.6, Quality Systems for Analytical Services 10.6c)*		